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08/446200

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/446,200	05/19/95	FREEMAN	G RPI-033

EXAMINER

18M1/1127

LAHIVE & COCKFIELD  
60 STATE STREET  
BOSTON MA 02109

EXAMINER  
ART UNIT PAPER NUMBER  
1816  
5

DATE MAILED: 11/27/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 0 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-59 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-59 are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Serial Number: 08/446200

Art Unit: 1816

### Part III DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has  
5 changed. To aid in correlating any papers for this application, all further  
correspondence regarding this application should be directed to Group Art Unit 1816,  
Examiner Evelyn Rabin, Ph.D.

#### *Election/Restriction*

10 2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11, drawn to a method of modulating a TH2 response,  
classified in Class 435, subclass 2 ~~and Class 530, subclasses 350,~~  
15 ~~388.22, and 391.1.~~

II. Claims 12-22, drawn to a 2 step method of activating involving 2 agents;  
a T cell activating agent and a B7-2 activating agent classified in Class  
435, subclasses 2 and 183 ~~and Class 530, subclasses 350, 388.75, and~~  
20 ~~391.1.~~

III. Claims 23-41, drawn to a method of treating a condition, classified in  
Class 424, subclasses 143.1, 178.1, 192.1, 265.1, and 810.

25 IV. Claims 42-53, drawn to a 2 step method of treatment: *ex vivo*  
modulation of a TH2 response using 2 agents and *in vivo* administration  
of activated cells, classified in Class 424, subclasses 94.1, 143.1, 154.1,  
178.1, 192.1, and 534.

Serial Number: 08/446200  
Art Unit: 1816

V. Claims 54, 55, and 58, drawn to a package form of stimulatory agent, classified in Class 424, subclasses 178.1 and 192.1 and ~~Class 530, subclasses 350 and 391.1.~~

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VI. Claims 56, 57, and 59, drawn to a package form of inhibitory agent, classified in Class 424, subclass 143.1 and ~~Class 530, subclass 388.1+.~~

10 3. Inventions I-IV are different methods of use. These inventions require different ingredients, process steps and endpoints to accomplish the use ~~of~~ . Therefore they are novel and unobvious in view of each other and are patentably distinct.

15 5. Inventions V and VI are different products. Antibodies and soluble receptors/fusion proteins are distinct because their structures and modes of action are different. Therefore they are novel and unobvious in view of each other and are patentably distinct.

20 7. Inventions V and I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product, soluble B7-2 receptor and fusion protein can be used in affinity columns to purify  
25 antibody.

8. Inventions VI and I, III, V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

Serial Number: 08/446200

Art Unit: 1816

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product can be used for detecting B7-2+ cells.

9. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Groups I and II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. **Irrespective of** whichever Group applicant may elect, applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

*or Group V or Group VI*

12. If Group I is elected, the election of a specific method of modulation encompassing a specific agent, wherein the specific agent is a stimulatory form of B7-2 attached to a solid phase support, a stimulatory form of B7-2 attached to cell, a soluble form of B7-2, a B7-2 fusion protein, a B7-2 -immunoglobulin fusion protein, a B7-2 inhibitor, or an anti-B7-2 antibody, is required.

13. These species are distinct because their structures and modes of action are different and the steps involved in the methods are different..

14. If Group II is elected, the election of a specific pair of agents is required.

Serial Number: 08/446200

Art Unit: 1816

15. These species are distinct because their structures and modes of action are different.

16. If Group III is elected, the election of a specific method for treating a specific condition encompassing administration of a specific agent is required.

17. These species are distinct because their structures and modes of action are different. Different steps in the methods and different etiologies for the diseases.

18. If Group IV is elected, the election of a specific method of ex vivo modulation encompassing a specific pair of reagents is required.

19. These species are distinct because their structures and modes of action are different. Different steps in methods.

20. Applicant is required to elect a single disclosed species in Groups I, II, III, ~~or~~ IV, V or VI, even though this requirement is traversed.

21. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

22. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R.

Serial Number: 08/446200  
Art Unit: 1816

§ 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

23. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

24. A telephone call and FAX transmission were made to Attorney Amy Mandragouras on August 13, 1996 to request an oral election to the above restriction, but did not result in an election being made.

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

26. Any inquiry concerning this communication should be directed to Evelyn Rabin, Ph.D. whose telephone number is (703) 305-6811. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.


27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The FAX number for this Group is (703) 305-7939. Any inquiry of a general nature or relating to the status

Serial Number: 08/446200  
Art Unit: 1816

of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Evelyn Rabin, Ph.D.

November 14, 1996

  
CHRISTINA Y. CHAN  
SUPERVISORY PATENT EXAMINER  
GROUP 1800